K113314

510(k) Summary

1. Submitter Information

NOV 9 2012

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Date Prepared:	Apr. 30, 2012

2. Name of Device

Trade/Proprietary Name:

	PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System
Common name:	Blood Glucose Test System
Classification name:	Glucose Test System
Classification Panel:	Clinical Chemistry (75)
Regulation no.:	862.1345 (Class II), 862.1660 (Class I)
Product code:	LFR, JJX
Panel:	Clinical Chemistry (75)

3. Predicate Device

Trade/Proprietary name:	SureStepFlexx Professional Blood Glucose Management System
Common name:	Blood Glucose Test System
Submitter:	Life Scan, Inc.
510(k) no.:	K023194
Product code:	NBW, CGA

Common name:	Glucose Control Solution
Submitter:	HMD Biomedical, Inc.
510(k) no.:	K032985
Product code:	JJX

4. Device Description

PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System consists of:

(1) Glucose Meter

(2) Glucose Test Strips

(3) Two levels of glucose control solutions (Level I and Level II) may be purchased separately. Glucose control solutions were previously cleared under K032985.

(4) Check Strip

(5) Instruction for use

[Test Principle]

The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is electrochemical biosensor system that measures the amount of electric current produced then displays the result as a blood glucose level on the LCD monitor.

When the blood is drawn into the blood reaction zone of the test strip, the glucose in the blood sample mixes with a special chemical in the test strip, which produces a small electric current. The reaction current is proportional to the amount of glucose in the blood. The result is displayed on the LCD monitor and automatically stored in the meter for future use.

[Control Solution]

The PRECICHEK Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals to

assess the performance of the PRECICHEK NS-101 POCT Professional Blood Glucose monitoring system and the PRECICHECK KP Blood Glucose Test strips. There are two levels of controls (Levels 1,2).

[Check Strip]

The Check Strip can be used to check that the meter is operating properly. It is composed of PCB, resistor, top cover and bottom cover.

[Device Calibration]

The device is calibrated by implicit coding process. The code number is the last two digits of the strip lot number. The user should input the strip lot number into the memory of the meter before use.

While performing the blood glucose test, the strip lot number printed on the vial label is scanned to match the one in the memory. The meter will apply formula including this parameter to calculate the glucose value.

5. Intended Use

PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System

The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, venous whole blood and arterial whole blood. The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This

system should only be used with single-use, auto-disabling lancing devices.

The PRECICHEK KP Blood Glucose Test Strip is for use with the PRECICHEK NS-101 POCT Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertips, venous whole blood and arterial whole blood.

The PRECICHEK Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals to assess the performance of the PRECICHEK NS-101 POCT Professional Blood Glucose monitoring system and the PRECICHECK KP Blood Glucose Test strips. There are two levels of controls (Levels 1, 2).

6. Comparison of Subject Devices and predicate device

Technological Characteristics Comparison Table of PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System and LifeScan SureStep Flexx Professional Blood Glucose Management System (K023194)

Item	**Subject Device** PRECICHEK NS-101 POCT Professional BGMS	**Predicate Device** LifeScan SureStep Flexx Professional BGMS
Similarities		
Indication of Use	It is designed to quantitatively measure the concentration of glucose (sugar) in capillary, venous, and arterial whole blood by healthcare professionals to monitor patient's blood glucose in clinical settings. The system is used outside the body (in vitro diagnostic).	Same
Code system	Bar code	Same

Blood sample source	Fresh whole blood (capillary, venous, arterial)	Same
Warming & Precaution	For *in-vitro* diagnostic use only	Same
Calibration	Plasma Equivalent	Same
Operating Procedure	Menu control Operational ID, Patient ID, Strip Lot	Same
Test Mode	Glucose Control Solution test, Capillary test, Venous test, Arterial test.	Same
Characteristics	For professional use only	Same
Differences		
Dimensions	143 x 65 x 33mm	161 x 90 x 41mm
Biological Source	Glucose Dehydrogenase	Glucose Oxidase
Principle	Electrical chemistry reaction	Photochemical Reaction
Blood sample volume	0.5uL	5-30uL
Buttons	Power, Scan, numbers	Power
Weight	200g (with battery)	375g (with battery)
Reaction time	5 seconds	30 seconds
Blood Glucose Range	20-600mg/dl	0-500 mg/dl
Operational Environment	10-40℃, 50-104℉ 20-80% RH	18-30℃, 64-86℉ 30-70%
Power Source	3.7V Li rechargeable via USB battery	3 AA 1.5v alkaline batteries

7. Discussion of Clinical Tests Performed

PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System (Subject Device) is compliant to the standard of ISO 15197:2003 In vitro diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. All the relevant activities were performed by professionals and

the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

   The subject device was tested to evaluate its safety and effectiveness, including the followings:

   (1) ISO 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

   (2) IEC 60601-1:1988 + A1:1991 + A2:1995 Medical electrical equipment - Part 1: General requirements for safety

   (3) IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility- Requirements and tests

   (4) CLSI/NCCLS EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods

   (5) CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement.

   (6) CLSI EP07-A2: Interference Testing in Clinical Chemistry

   (7) CLSI/NCCLS EP09-A2: Method Comparison and Bias Estimation Using Patient Samples

   (8) FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

9. Conclusion

   The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 9, 2012

HMD Biomedical Inc.
c/o Wang Yunhan
No. 181, Minsheng St
Xinpu Township, Hsinchu County
Taiwan

Re: k113314
Trade/Device Name: PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: LFR, JJX
Dated: October 26, 2012
Received: October 31, 2012

Dear Wang Yunhan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113314

Device Name [Trade Name]:

PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System

Indications for Use:

The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary drawn from the fingertips, venous and arterial whole blood samples. The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by health care professionals in a clinical setting.

The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The PRECICHEK NS-101 POCT Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The PRECICHEK KP Blood Glucose Test Strip is for use with the PRECICHEK NS-101 POCT Professional Blood Glucose Meter to quantitatively measure glucose in fresh capillary drawn from the fingertips, venous and arterial whole blood samples.

The PRECICHEK Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals to assess the performance of the PRECICHEK NS-101 POCT Professional Blood Glucose monitoring system and the PRECICHECK KP Blood Glucose Test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use V (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113314